# AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 534, as Reported

**[Greenwood, Deutsch, DeGette, Kirk, Eshoo, Schiff Amendment]**

6

## OFFERED BY MR. GREENWOOD OF PENNSYLVANIA

Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE.**

This Act may be cited as the "Cloning Prohibition Act of 2003".

**SEC. 2. PROHIBITION AGAINST HUMAN CLONING.**

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended by adding at the end the following:

"CHAPTER X—HUMAN CLONING

"PROHIBITION AGAINST HUMAN CLONING

"SEC. 1001. (a) NUCLEAR TRANSFER TECHNOLOGY.—

"(1) IN GENERAL.—It shall be unlawful for any person—

"(A) to use or attempt to use human somatic cell nuclear transfer technology, or the product of such technology, to initiate a preg-

nancy or with the intent to initiate a pregnancy; or

"(B) to ship, mail, transport, or receive the product of such technology knowing that the product is intended to be used to initiate a pregnancy.

"(2) DEFINITION.—For purposes of this section, the term 'human somatic cell nuclear transfer technology' means transferring the nuclear material of a human somatic cell into an egg cell from which the nuclear material has been removed or rendered inert.

"(b) RULE OF CONSTRUCTION.—This section may not be construed as applying to any of the following:

"(1) The use of somatic cell nuclear transfer technology to clone molecules, DNA, cells, or tissues.

"(2) The use of mitochondrial, cytoplasmic, or gene therapy.

"(3) The use of in vitro fertilization, the administration of fertility-enhancing drugs, or the use of other medical procedures (excluding those using human somatic cell nuclear transfer or the product thereof) to assist a woman in becoming or remaining pregnant.

"(4) The use of somatic cell nuclear transfer technology to clone or otherwise create animals other than humans.

"(5) Any other activity (including biomedical, microbiological, or agricultural research or practices) not expressly prohibited in subsection (a).

"(c) REGISTRATION.—

"(1) IN GENERAL.—Each individual who intends to perform human somatic cell nuclear transfer technology shall, prior to first performing such technology, register with the Secretary his or her name and place of business (except that, in the case of an individual who performed such technology before the date of the enactment of the Cloning Prohibition Act of 2003, the individual shall so register not later than 60 days after such date). The Secretary may by regulation require that the registration provide additional information regarding the identity and business locations of the individual, and information on the training and experience of the individual regarding the performance of such technology.

"(2) ATTESTATION BY RESEARCHER.—A registration under paragraph (1) shall include a statement, signed by the individual submitting the reg-

istration, declaring that the individual is aware of the prohibitions described in subsection (a) and will not engage in any violation of such subsection.

"(3) CONFIDENTIALITY.—Information provided in a registration under paragraph (1) shall not be disclosed to the public by the Secretary except to the extent that—

"(A) the individual submitting the registration has in writing authorized the disclosure; or

"(B) the disclosure does not identify such individual or any place of business of the individual.

"(d) APPLICABILITY OF HUMAN SUBJECT PROTECTION STANDARDS.—

"(1) IN GENERAL.—Research involving human somatic cell nuclear transfer technology shall be conducted in accordance with parts 50 and 56 of title 21, Code of Federal Regulations, subject to paragraph (2). Individuals whose cells are used for such research shall be considered human subjects for purposes of such parts.

"(2) INFORMED CONSENT.—

"(A) DONOR OF HUMAN CELLS.—In research involving human somatic cell nuclear

transfer technology, human cells may be used only if, in addition to requirements that apply under parts 50 and 56 of title 21, Code of Federal Regulations, the individual who provides the cells makes a statement in writing, which is signed by the individual, declaring that—

"(i) the individual donates the cells for purposes of such research;

"(ii) the individual understands that Federal law regulates such technology and establishes a crime relating to the use of the technology to initiate a pregnancy; and

"(iii) the individual does not intend for the cells to be used to initiate a pregnancy.

"(B) ATTESTATION BY RESEARCHERS.—In research involving human somatic cell nuclear transfer technology, human cells may be used only if, in addition to requirements that apply under parts 50 and 56 of title 21, Code of Federal Regulations, the individual with the principal responsibility for conducting the research makes a statement in writing, which is signed by the individual, declaring that the consent of the donor of the cells for the cells to be used

in such research was obtained in accordance with this subsection.

"(e) PREEMPTION OF STATE LAW.—This section supersedes any State or local law that—

"(1) establishes prohibitions, requirements, or authorizations regarding human somatic cell nuclear transfer technology that are different than, or in addition to, those established in subsection (a) or (c); or

"(2) with respect to humans, prohibits or restricts research regarding or practices constituting—

"(A) somatic cell nuclear transfer;

"(B) mitochondrial or cytoplasmic therapy; or

"(C) the cloning of molecules, DNA, cells, tissues, or organs;

except that this subsection does not apply to any State or local law that was in effect as of the day before the date of the enactment of the Cloning Prohibition Act of 2003.

"(f) RIGHT OF ACTION.—This section may not be construed as establishing any private right of action.

"(g) DEFINITION.—For purposes of this section, the term 'person' includes governmental entities.

"(h) SUNSET.—This section and section 301(hh) do not apply to any activity described in subsection (a) that occurs on or after the expiration of the 10-year period beginning on the date of the enactment of the Cloning Prohibition Act of 2003.".

(b) PROHIBITED ACTS.—

(1) IN GENERAL.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

"(hh) The violation of section 1001(a), or the failure to register in accordance with section 1001(c).".

(2) CRIMINAL PENALTY.—Section 303(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(b)) is amended by adding at the end the following:

"(7) Notwithstanding subsection (a), any person who violates section 301(hh) shall be imprisoned not more than 10 years or fined in accordance with title 18, United States Code, or both.".

(3) CIVIL PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

"(h)(1) Any person who violates section 301(hh) or section 1001(d) shall be liable to the United States for a civil penalty in an amount not to exceed the greater of—

"(A) $10,000,000; or

"(B) an amount equal to the amount of any gross pecuniary gain derived from such violation multiplied by 2.

"(2) Paragraphs (3) through (5) of subsection (g) apply with respect to a civil penalty under this subsection to the same extent and in the same manner as such paragraphs (3) through (5) apply with respect to a civil penalty under subsection (g).".

(4) FORFEITURE.—Section 303 of the Federal Food, Drug, and Cosmetic Act, as amended by paragraph (3), is amended by adding at the end the following:

"(i) Any property, real or personal, derived from or used to commit a violation of section 301(hh), or any property traceable to such property, shall be subject to forfeiture to the United States.".

**SEC. 3. STUDY BY INSTITUTE OF MEDICINE.**

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall request the Institute of Medicine to enter into an agreement with the Secretary under which such Institute conducts a study to—

(1) review the current state of knowledge about the biological properties of stem cells obtained from embryos, fetal tissues, and adult tissues;

(2) evaluate the current state of knowledge about biological differences among stem cells obtained from embryos, fetal tissues, and adult tissues and the consequences for research and medicine; and

(3) assess what is currently known about the ability of stem cells to generate neurons, heart, kidney, blood, liver and other tissues and the potential clinical uses of these tissues.

(b) OTHER ENTITIES.—If the Institute of Medicine declines to conduct the study described in subsection (a), the Secretary shall enter into an agreement with another appropriate public or nonprofit private entity to conduct the study.

(c) REPORT.—The Secretary shall ensure that, not later than three years after the date of the enactment of this Act, the study required in subsection (a) is completed and a report describing the findings made in the study is submitted to the Committee on Energy and Commerce in the House of Representatives and the Committee on Health, Education, Labor, and Pensions in the Senate.